FDA- REQUIRED REMS SAFETY INFORMATION

- Risk of Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) with **TECVAYLI**
- Required REMS Certification to prescribe **TECVAYLI**

Dear Healthcare Provider:

The purpose of this letter is to inform you of important safety information for **TECVAYLI** based on current prescribing information. FDA has required this safety notice as part of the **TECVAYLI** REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform you about the serious risks of CRS and neurologic toxicity, including ICANS.

Serious Risks of TECVAYLI

- **Cytokine release syndrome (CRS)**, including life-threatening or fatal reactions, can occur in patients receiving **TECVAYLI**.
- Initiate treatment with TECVAYLI step-up dosing schedule to reduce risk of CRS.
- **Neurologic toxicity, including ICANS** and serious and life-threatening reactions, can occur in patients receiving **TECVAYLI**.
- Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment.
- Withhold **TECVAYLI** until CRS or neurologic toxicity, including ICANS, resolves or permanently discontinue based on severity.

Enclosed for your review and awareness of these serious risks is the ***TECVAYLI REMS Fact Sheet***, a non-promotional Fact Sheet reviewed by the FDA which will provide you with more information about these risks and the **TECVAYLI** REMS requirements.

REMS Requirements

- Those who prescribe and/or dispense **TECVAYLI** must be aware of how to manage the risks of CRS and neurologic toxicity, including ICANS.
- **TECVAYLI** is ONLY prescribed and/or dispensed by certified prescribers, pharmacies, and healthcare settings.
- Prescribers must counsel patients on signs and symptoms of CRS and neurologic toxicity, including ICANS.
- Complete the ***Patient Wallet Card*** for the patient or caregiver and provide it to them.

Indication

TECVAYLI is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Adverse Event Reporting

Healthcare providers must report any serious adverse events suggestive of CRS and neurologic toxicity, including ICANS, to Janssen Biotech, Inc. at 1-800-Janssen (1-800-526-7736) or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

For a complete safety profile of **TECVAYLI**, please see the **Prescribing Information** included. For additional details about the REMS, please visit **www.TECVAYLIREMS.com** or contact the **TECVAYLI** REMS Coordinating Center at 1-855-810-8064.

Sincerely,

Janssen Biotech, Inc.

TECVAYLI™ (teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

Janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson&Johnson